Accelerating Precision Health for All of Us

The All of Us *Research Program*

NIAMS Coalition Outreach & Education Meeting
October 17, 2017

Eric Dishman

Entrepreneurial Patient, Advocate, Caregiver

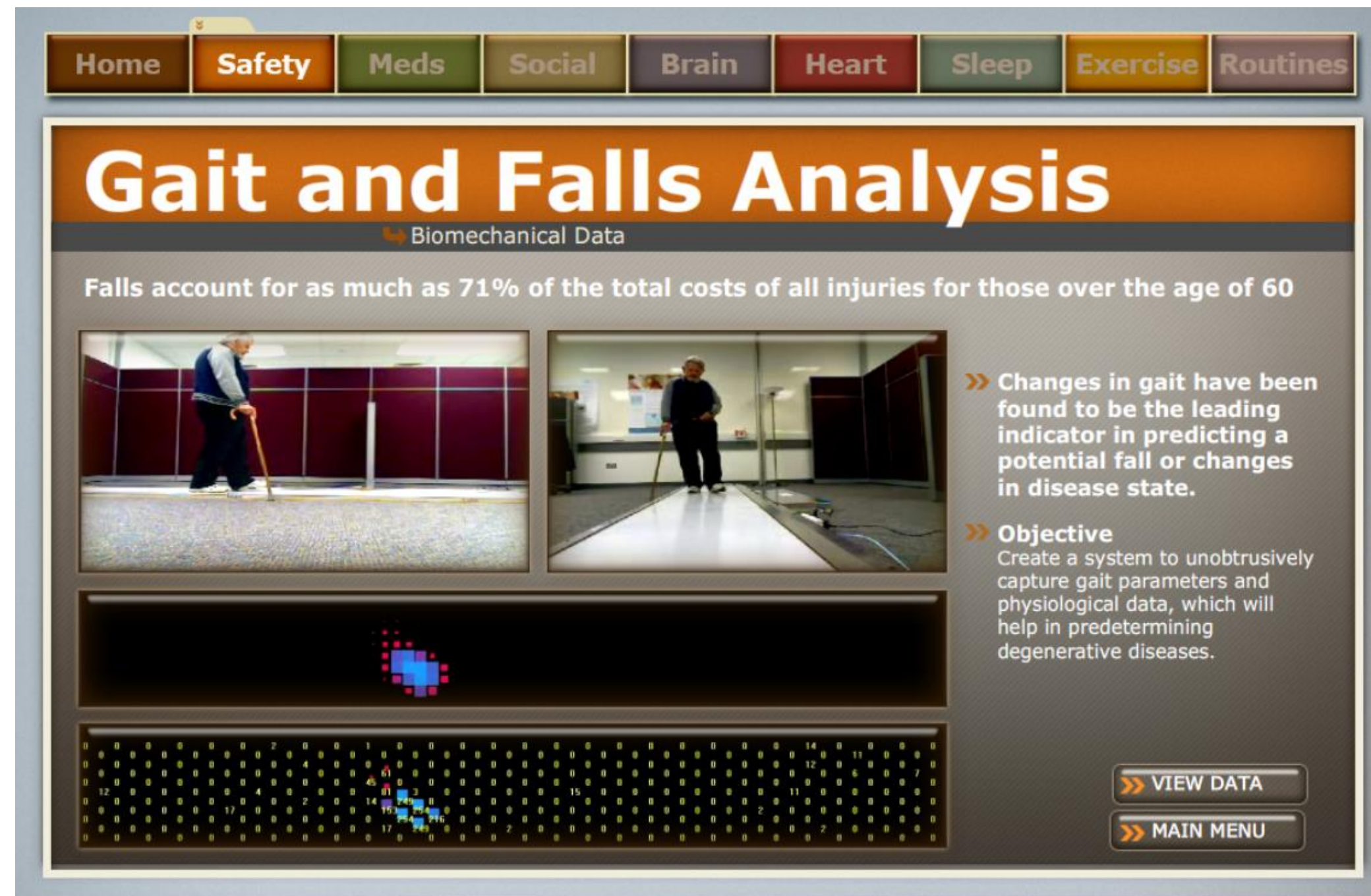Director, *All of Us* Research Program

NIH
National Institutes
of Health

Creating health for an individual became a passion at age 16, as a caregiver for a grandmother with severe arthritis (and another with Alzheimer's).

As a social scientist, my focus of 14 years of fieldwork was studying older people, especially with regards to maintaining movement, activity, and activities of daily living.

Initial wearable platforms for researching movement 15 years ago…

Can we provide data back to individuals and families that helps with their quality of life, such as doing the things that give them purpose & independence?

Can sensing microscopic changes in patterns of physical movement help with the early detection & differentiation of diseases? Can we stop a fall before it happens?

Mission & Objectives of the *All of Us* Research Program

All of Us Mission and Objectives

Nurture relationships

with one million or more participant partners, from all walks of life, for decades

Deliver the largest, richest biomedical dataset ever

that is easy, safe, and free to access

Our mission

To accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us
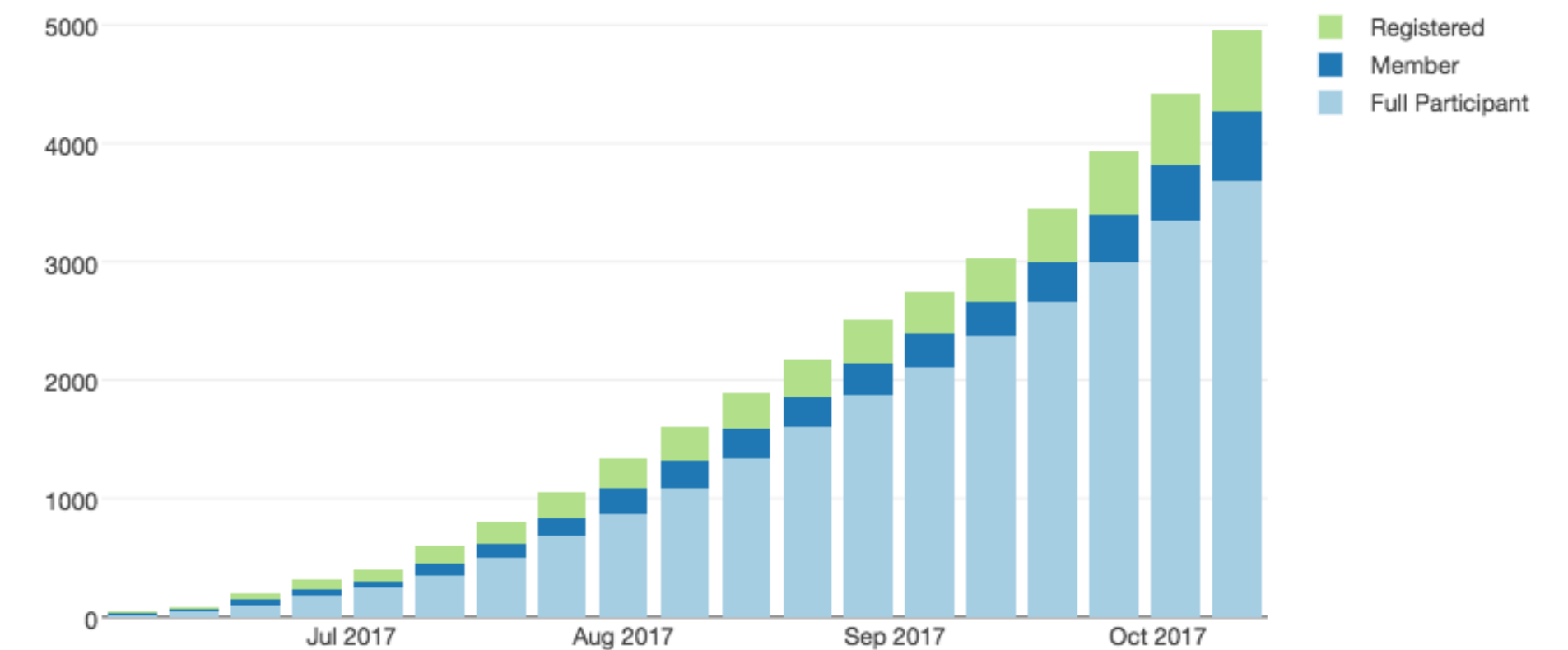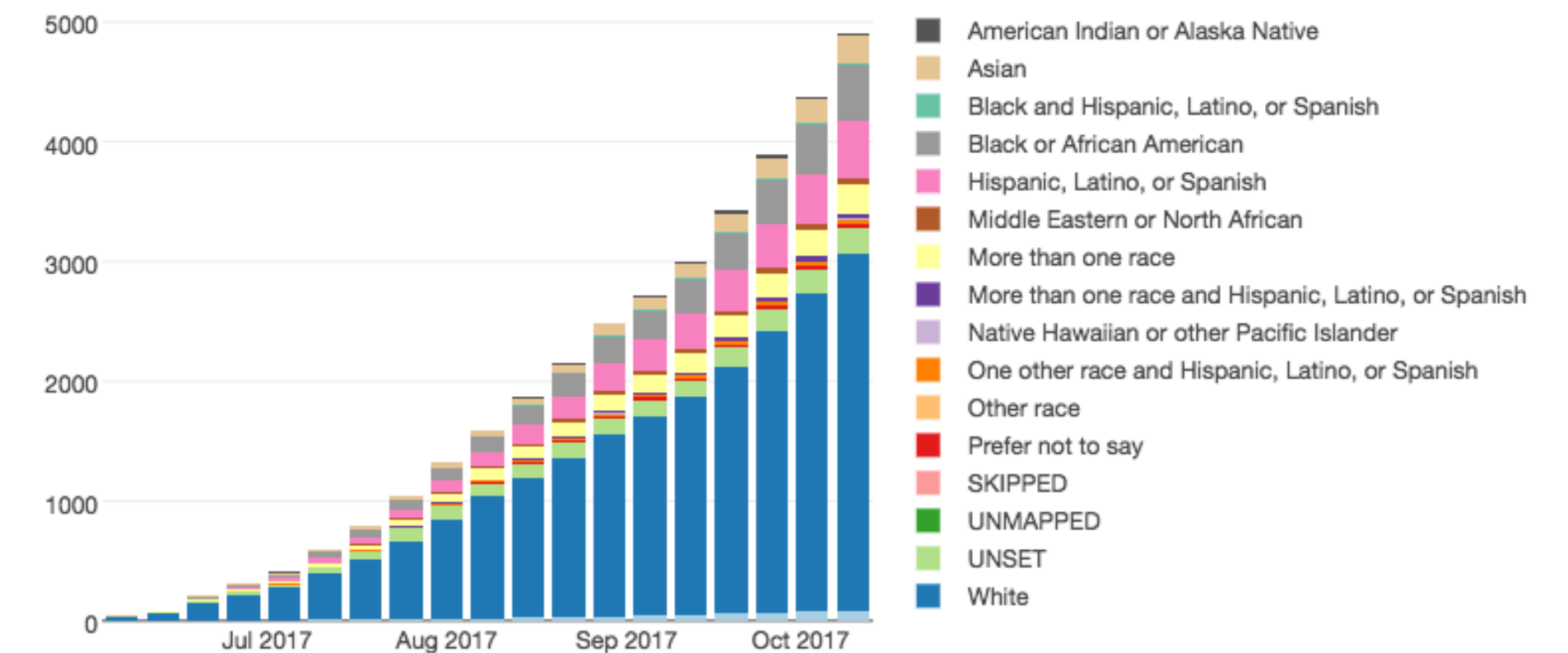
Catalyze the robust ecosystem

of researchers and funders hungry to use and support it

Since I visited NIAMS council in June…

- ◎ Launched 50+ sites

- ◎ Enrolled more than 3,000 full participants

  - Pittsburgh and Arizona both enrolled 1,000+ participants

  - Both HPO & DV paths are launched

- ◎ Announced 3 new HPOs and 4 new community partners

- ◎ Deployed updates and improvements to the participant portal & HealthPro staff tools

- ◎ Maintained operations at the Support Center, even in the face of natural disasters (STOP with the hurricanes!)

- ◎ Launched Children's Enrollment Scientific Vision WG, Genomics WG

- ◎ Progress on assays definition and initial pilot of ROR

- ◎ Kicked off mobile exhibit, the *All of Us* Journey

Count of **enrollment status** by date

Legend:
- Registered
- Member
- Full Participant

Count of **race** by date

Legend:
- American Indian or Alaska Native
- Asian
- Black and Hispanic, Latino, or Spanish
- Black or African American
- Hispanic, Latino, or Spanish
- Middle Eastern or North African
- More than one race
- More than one race and Hispanic, Latino, or Spanish
- Native Hawaiian or other Pacific Islander
- One other race and Hispanic, Latino, or Spanish
- Other race
- Prefer not to say
- SKIPPED
- UNMAPPED
- UNSET
- White

Current Consortium Members

DV Network
(Direct Volunteers)

Scripps Translational Science Institute | NATIONAL BLOOD COLLABORATIVE Blood Solutions | Trusted Source | QTC A Leidos Company | Walgreens | BlueCross BlueShield | WONDROS

DXC.technology | Quest Diagnostics | EMSI HEALTH | patientslikeme | WebMD | HCM STRATEGISTS

HPO Network
(Health Care Provider Organizations)

RMCs

California Precision Medicine Consortium

UC San Diego Health

UCDAVIS HEALTH | Keck Medical Center of USC

UC Irvine Health

UC HEALTH | UCSF University of California San Francisco

San Diego Blood Bank | CEDARS-SINAI

Illinois Precision Medicine Consortium

Northwestern University

THE UNIVERSITY OF CHICAGO

NorthShore University HealthSystem

RUSH

THE UNIVERSITY OF ILLINOIS AT CHICAGO | UIC

New England Precision Medicine Consortium

PARTNERS HEALTHCARE

MGH MASSACHUSETTS GENERAL HOSPITAL

BRIGHAM HEALTH | BWH BRIGHAM AND WOMEN'S HOSPITAL

BU Boston University School of Medicine

BOSTON MEDICAL CENTER EXCEPTIONAL CARE. WITHOUT EXCEPTION.

University of Massachusetts UMASS Medical School

Trans-American Consortium for the Health Care Systems Research Network

Henry Ford HEALTH SYSTEM

Essentia Health

BaylorScott&White HEALTH

SPECTRUM HEALTH

New York City Precision Medicine Consortium

COLUMBIA UNIVERSITY MEDICAL CENTER

NYC HEALTH+ HOSPITALS

NewYork-Presbyterian

Weill Cornell Medicine

Southern
All of Us Network

UAB SCHOOL OF MEDICINE Knowledge that will change your world | UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM Knowledge that will change your world

The University of Mississippi MEDICAL CENTER | UAB MEDICINE UAB HOSPITAL

Tulane University | TUSKEGEE UNIVERSITY | Cooper Green Mercy HEALTH SERVICES

Huntsville Hospital | University Medical Center

USA UNIVERSITY OF SOUTH ALABAMA HEALTH SYSTEM | LSU Health NEW ORLEANS

SouthEast Enrollment Center

UHealth UNIVERSITY OF MIAMI HEALTH SYSTEM | UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE

EMORY UNIVERSITY

MOREHOUSE SCHOOL OF MEDICINE

OneFlorida Clinical Research Consortium

VA Medical Centers

All of Us, Wisconsin

Marshfield Clinic | CLEMENT J. ZABLOCKI VA MEDICAL CENTER | University of Wisconsin SCHOOL OF MEDICINE AND PUBLIC HEALTH | MEDICAL COLLEGE OF WISCONSIN

BloodCenter of Wisconsin PART OF VERSITI

University of Arizona

THE UNIVERSITY OF ARIZONA

Banner Health

University of Pittsburgh

University of Pittsburgh

FQHCs (Federally Qualified Health Centers)

Cherokee HEALTH SYSTEMS | JACKSON-HINDS COMPREHENSIVE HEALTH CENTER | San Ysidro Health Center | HRHCare COMMUNITY HEALTH

Community Health Center, Inc. | Eau Claire Cooperative Health Center People is Care do better.

VA | U.S. Department of Veterans Affairs

Community Partners

DELTA RESEARCH AND EDUCATIONAL FOUNDATION CREATING POSSIBILITIES... IMPROVING LIVES | National Alliance for Hispanic Health | Fifty Forward | SAN FRANCISCO GENERAL HOSPITAL FOUNDATION

Communication & Engagement

WONDROS | HCM STRATEGISTS

Platform Development

Scripps Translational Science Institute | Sage BIONETWORKS | VANDERBILT UNIVERSITY | WONDROS | vibrent

Program Development Timeline – to National Launch

Kickoff Meeting w/Implementation Awardees *July 6–8, 2016*

WE ARE HERE!

2015	2016	2017	2018

Vision
January–September 2015

- SOTU by President Obama (*Jan. 2015*)
- ACD (Advisory Committee to the (NIH) Director)
  - PMI Working Group formed (*Mar. 2015*)
  - Held 4 workshops to gather input from researchers, public on scientific opportunities, digital health data, participant engagement, and mobile technology (*May-July 2015*)
  - Published 2 RFIs – 221 respondents (*Apr. 2015*)
  - Report/recommendations (*Sept. 2015*)
- Public opinion survey conducted – 2601 responses (*May-June 2015*)

Planning & Prototype Piloting
Fall 2015–Fall 2016

NIH wrote implementation papers, began staffing up

Vanderbilt pilot project: Built prototype infrastructure & group of 5000+ for feedback on enrollment/engagement, consent, surveys, and return of results (*awarded Feb. 2016*)

Sync for Science pilot (*awarded Feb. 2016*)

Communications awardees began research, campaign planning, and content development (*awarded Mar. 2016*)

Director (Eric Dishman) started (*June 2016*)

Implementation & Development Phase
Fall 2016–Spring 2017

Built network of health care provider organizations to support enrollment & retention

Direct volunteer partners in place w/community awards planned

Establishment of Support Center for participants (toll-free number/email, etc.)

Biobank building/robots & 24-hour shipping process

Protocol developed for Version 1 / approved by IRB

Development of website and participant portal—internet, iOS and Android app

Development of data warehouse

Development of software for providers/assistants to transmit data from participants' in-person visits

Security testing & usability testing

Congress passes H.R.34, 21st Century Cures Act, in Dec with bipartisan support. Provides funding, strengthens data sharing & privacy provisions

Closed Beta Phase for Version 1 Platform & Protocol
Summer–Fall 2017

Real infrastructure, protocol, people.

Expanded Beta Phase
Fall 2017–Early 2018

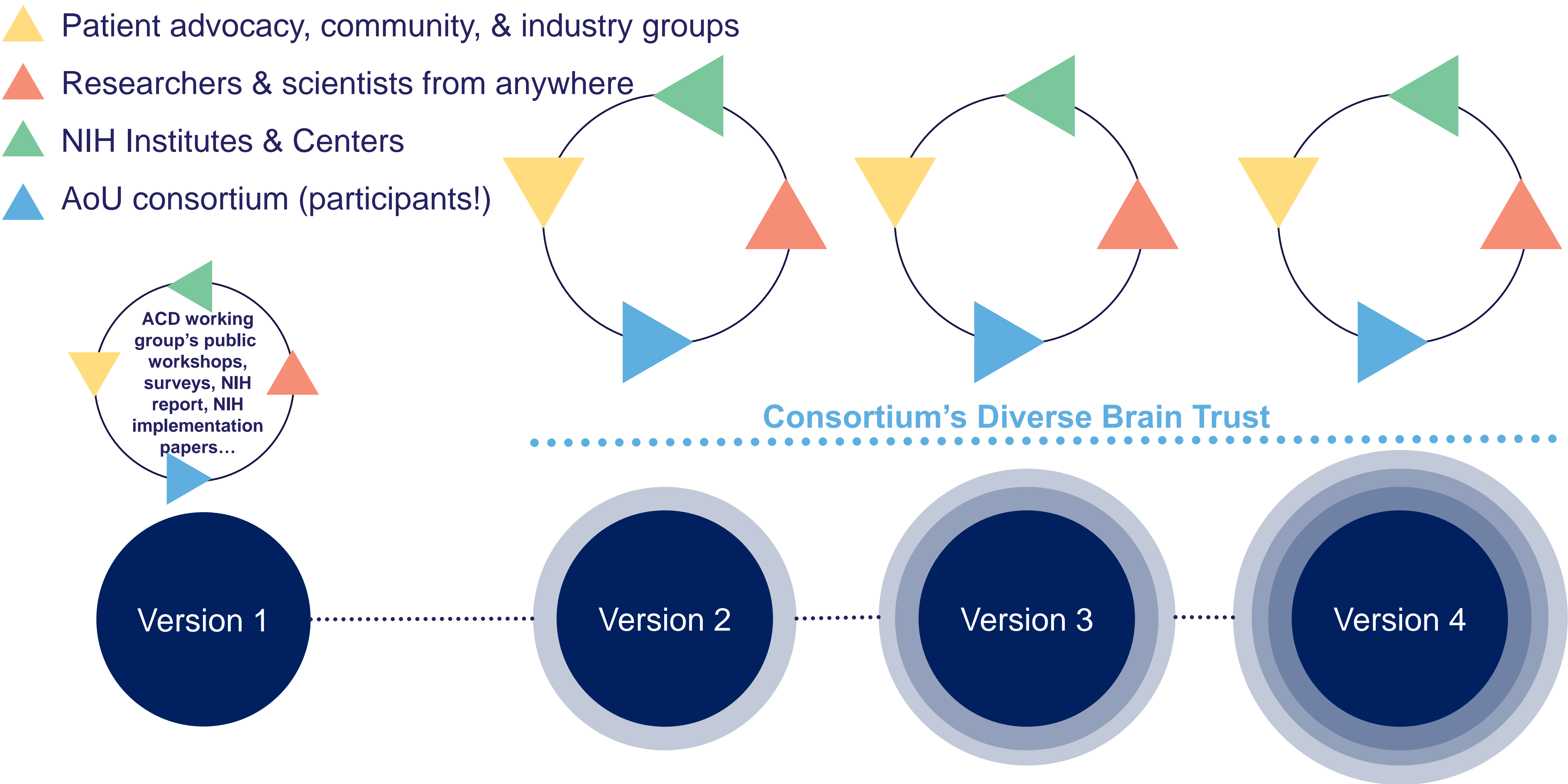Expanded testing of diversity engine, infrastructure; increase scientific capabilities.

National Launch
Early 2018

If ready and right and all things worked well in beta phase

Getting ongoing input to drive questions & discoveries

Need a way to do/drive ongoing scientific requirements gathering

▲ Patient advocacy, community, & industry groups

▲ Researchers & scientists from anywhere

▲ NIH Institutes & Centers

▲ AoU consortium (participants!)

ACD working group's public workshops, surveys, NIH report, NIH implementation papers…

Consortium's Diverse Brain Trust

Version 1

Version 2

Version 3

Version 4

Liaisons Coordinating Team (LCT) Members

- ◉ Co-chairs
  - Robert Carter, NIAMS ⬅ Thank you!
  - Stephanie Devaney, AOU
  - Carolyn Hutter, NHGRI
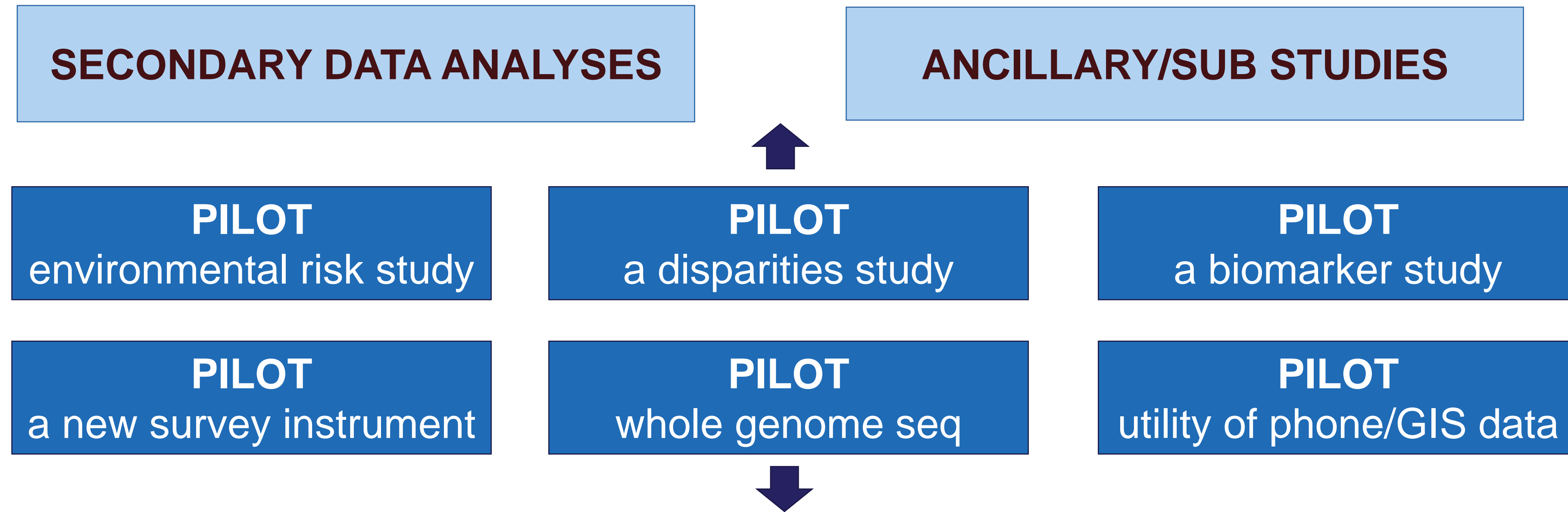
- ◉ Members
  - AOU: Joni Rutter, AOU
  - ECHO: Carol Blaisdell
  - NCATS: Anne Pariser
  - NCCIH: Robin Elizabeth Boineau
  - NCI: Montserrat Garcia-Closas
  - NEI: Ellen Liberman
  - NHLBI: Gina S. Wei
  - NIA: Marie Bernard
  - NIAAA: Joanne Fertig
  - NIAID: Robert Eisinger
  - NIBIB: Edward Ramos
  - NICHD: Catherine Spong
  - NIDA: Maureen Boyle

- NIDCD: Bracie Watson, Jr.
- NIDCR: Jane C. Atkinson
- NIDDK: Judith Fradkin
- NIEHS: Janet Hall
- NIGMS: Rochelle Long
- NIMH: Shelli Avenevoli
- NIMHD: Regina James
- NINDS: Clinton Wright
- NINR: Michelle Hamlet
- NLM: Dianne Babski
- OAR: Stacy Carrington-Lawrence
- OBSSR: Dana Wolff-Hughes
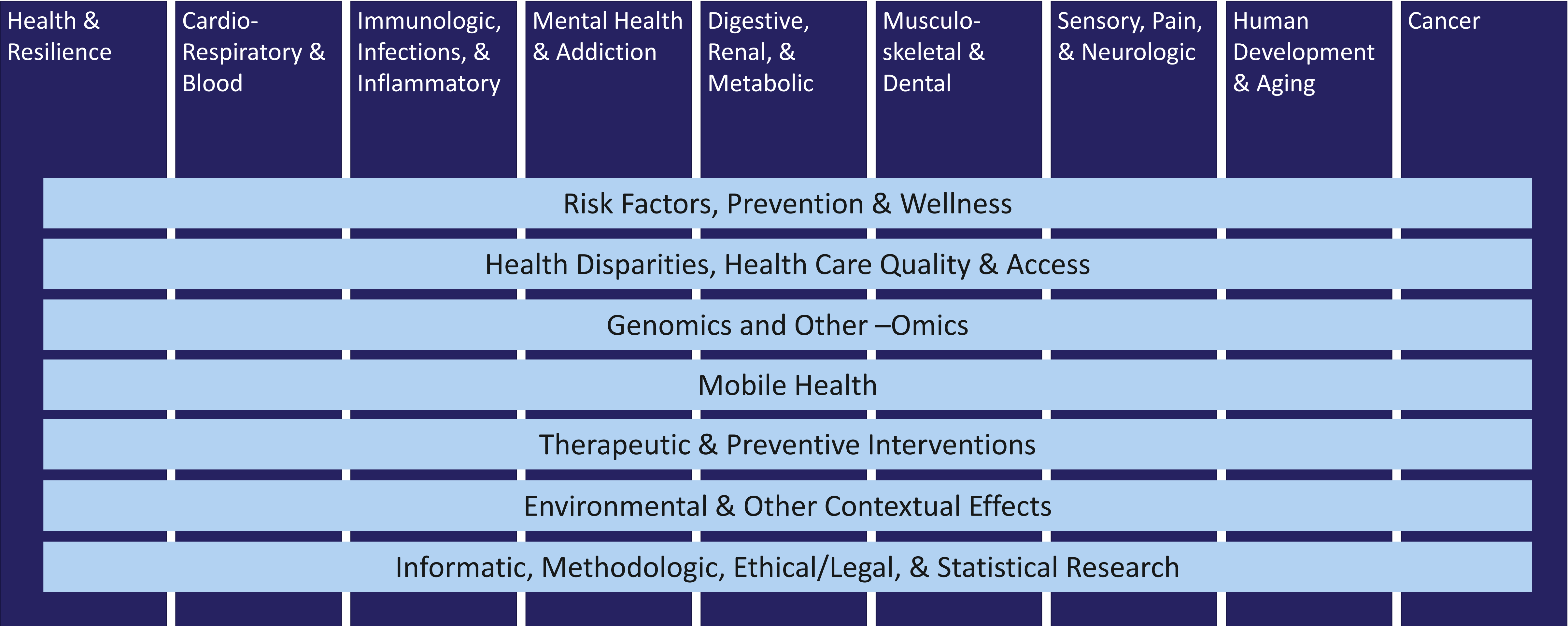- ODP: Sheri Schully
- ORWH: Denise Stredrick

- ◉ Non-voting Members
  - Allison Lea, OSP
  - Stephen Mockrin, AOU
  - Debbie Winn, NCI

All of Us is building a Resource for others to drive their science

SECONDARY DATA ANALYSES	ANCILLARY/SUB STUDIES

PILOT
environmental risk study

PILOT
a disparities study

PILOT
a biomarker study

PILOT
a new survey instrument

PILOT
whole genome seq

PILOT
utility of phone/GIS data

V1 platform
Data
Samples
Analyses
Tools
Cohort

V2 platform
+ Data
+ Samples
+ Analyses
+ Tools
+ Cohort

V3 platform
+ Data
+ Samples
+ Analyses
+ Tools
+ Cohort

Vx platform…
…
…
…
…
…

Scientific Framework for the *All of Us* March 2018 Workshop

Health & Resilience	Cardio-Respiratory & Blood	Immunologic, Infections, & Inflammatory	Mental Health & Addiction	Digestive, Renal, & Metabolic	Musculo-skeletal & Dental	Sensory, Pain, & Neurologic	Human Development & Aging	Cancer
Risk Factors, Prevention & Wellness								
Health Disparities, Health Care Quality & Access								
Genomics and Other –Omics								
Mobile Health								
Therapeutic & Preventive Interventions								
Environmental & Other Contextual Effects								
Informatic, Methodologic, Ethical/Legal, & Statistical Research								

Developed with NIH IC Input

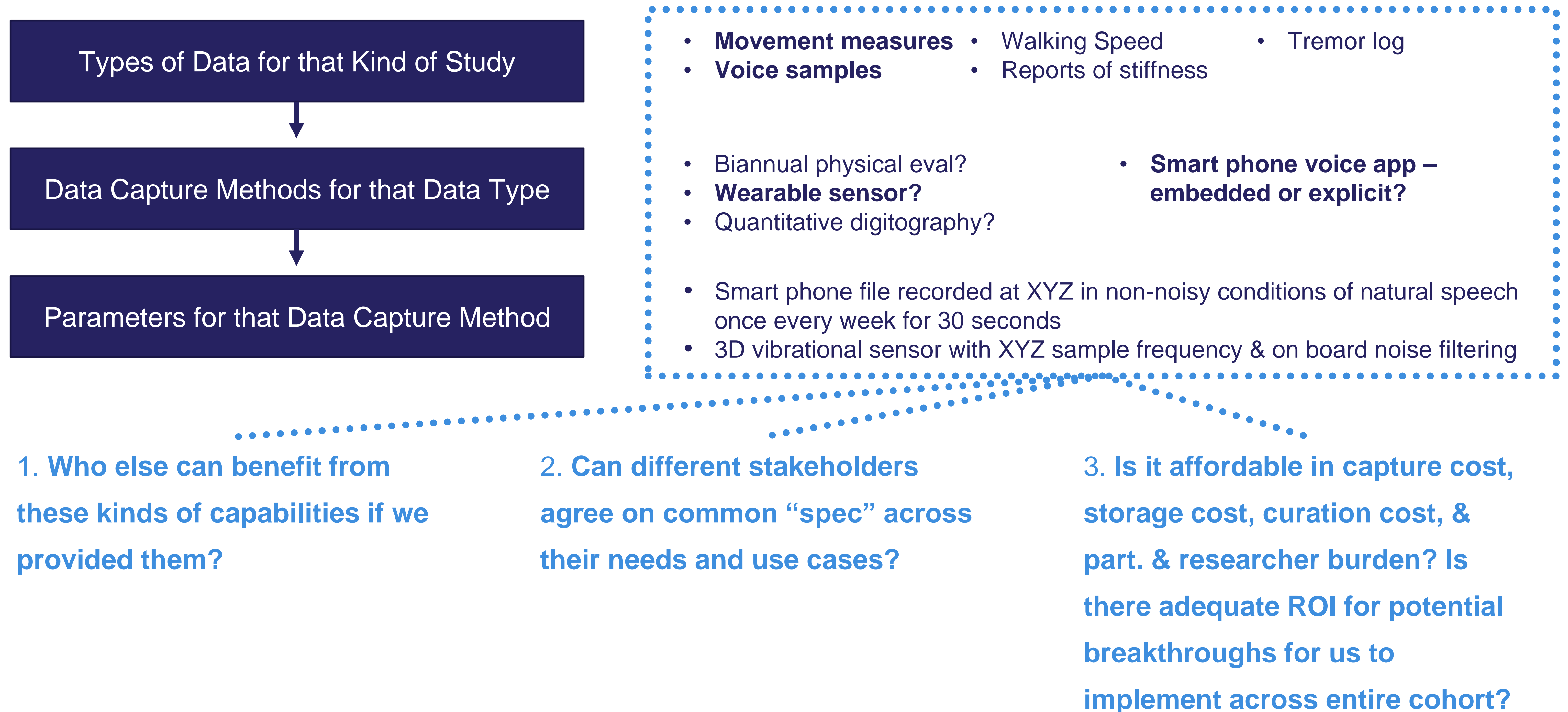Verticals = High level condition/disease areas; Horizontals = Cross cutting areas of interest / themes

Framework for requirements generation

Priority Area for XYZ biomedical field

↓

Research Questions for Priority Area

↓

Kinds of Studies for That Research Question

↓

Types of Data for that Kind of Study

↓

Data Capture Methods for that Data Type

↓

Parameters for that Data Capture Method

Framework for requirements generation: A neuromuscular example

Priority Area for XYZ biomedical field

- Priority area: Neuromuscular disorders (lots of them)
- Research opportunity: **Early detection & progression monitoring?**

Research Questions for Priority Area

- Chemical changes?
- **Movement & ADL changes?**
- Cognitive Changes?
- Genetic risk factors?
- Microbiomic causes?
- **Voice changes?**

Kinds of Studies for That Research Question

- Diary on movement changes?
- **Physical exam on range of motion?**
- **Test voice energy & fundamental frequency variability?**

Types of Data for that Kind of Study

- **Movement measures**
- **Voice samples**
- Walking Speed
- Reports of stiffness
- Tremor log

Data Capture Methods for that Data Type

- Biannual physical eval?
- **Wearable sensor?**
- Quantitative digitography?
- **Smart phone voice app – embedded or explicit?**

Parameters for that Data Capture Method

- Smart phone file recorded at XYZ in non-noisy conditions of natural speech once every week for 30 seconds
- 3D vibrational sensor with XYZ sample frequency & on board noise filtering

Framework for requirements generation: A neuromuscular example

Types of Data for that Kind of Study

↓

Data Capture Methods for that Data Type

↓

Parameters for that Data Capture Method

- **Movement measures**
- **Voice samples**
  - Walking Speed
  - Reports of stiffness
  - Tremor log

- Biannual physical eval?
- **Wearable sensor?**
- Quantitative digitography?
  - **Smart phone voice app – embedded or explicit?**

- Smart phone file recorded at XYZ in non-noisy conditions of natural speech once every week for 30 seconds
- 3D vibrational sensor with XYZ sample frequency & on board noise filtering

1. **Who else can benefit from these kinds of capabilities if we provided them?**

2. **Can different stakeholders agree on common "spec" across their needs and use cases?**

3. **Is it affordable in capture cost, storage cost, curation cost, & part. & researcher burden? Is there adequate ROI for potential breakthroughs for us to implement across entire cohort?**

Most helpful thing you can do for your areas of interest? Requirements, requirements, requirements

A vision for "more than a million"…

Growing beyond one million: #1 – Efficiency and advocacy

All of Us

Growing beyond one million: #2 – Franchise model
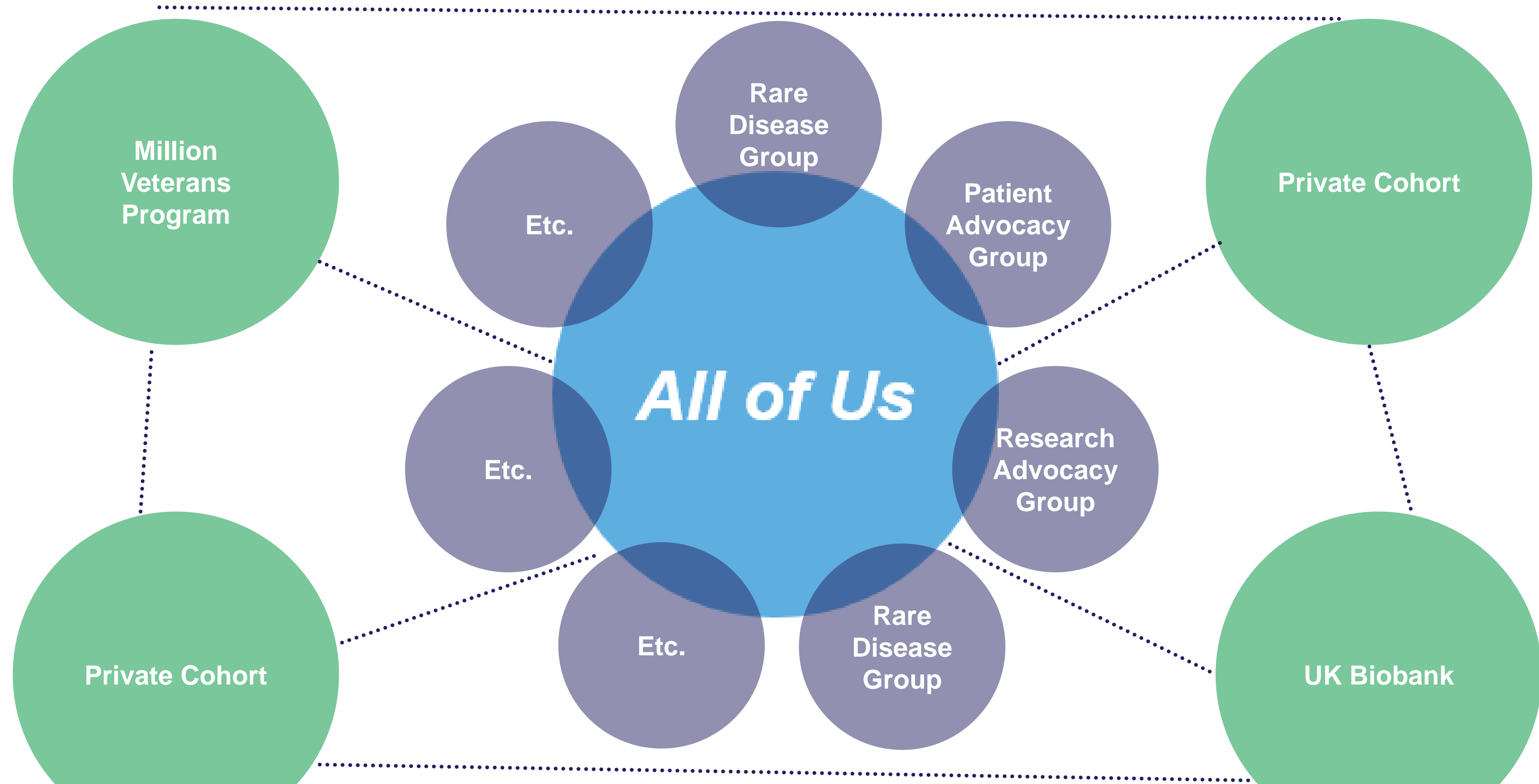
Opportunity for many other kinds of partnerships over time…but we are focusing on launch first! ☺

Questions?

- **NIH website** – with new design, new content, Director's Corner, and form to sign up for email updates: https://allofus.nih.gov

- **Enrollment site**: JoinAllofUs.org

- **Follow us on social media**: @AllofUsResearch, @ericdishman, #JoinAllofUs

Thank You!

Partnering with *All of Us*

Supporting the Program – Now

- Share information about *All of Us* in your newsletters, emails and via social media
- Incorporate *All of Us* into your community conversations about research
- Feature *All of Us* at local, regional, or national events of conferences
- Host the *All of Us* Journey in your community

Supporting the Program – Launch and Beyond

⦿ Provide a formal endorsement of *All of Us*

⦿ Sign your organization up to be a part of the Spokesperson's Pool

⦿ Develop a community ambassador program

⦿ Host awareness, education and enrollment events

Engagement Assets for Partner Organizations

Program Fact Sheet

Videos
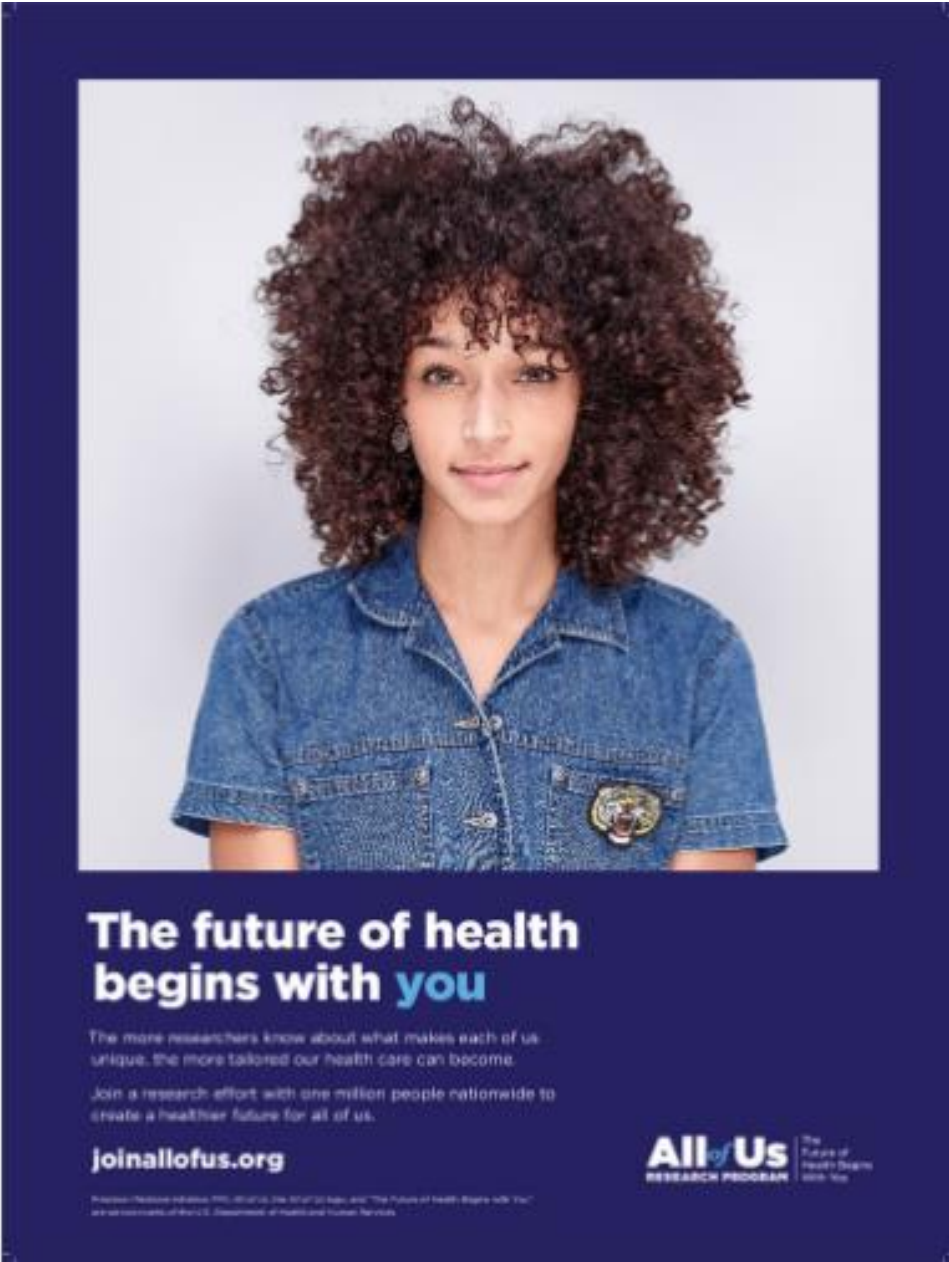
Posters

Digital Banners

All of Us **Journey**

Next steps

If your organization is interested in learning more, keeping up to date on program developments, or becoming a community partner, let us know!

Contact:

Kim Cantor, HCM Strategists
Kim_Cantor@hcmstrategists.com

Approved *All of Us* Version 1 Protocol

Summary: Approved Version 1 of Protocol

Enroll, Consent & EHR

- Recruit 18+ years old initially; plan to include children in next iteration
- eConsent or paper long-form
- Participants complete additional consent to share EHR data

Surveys

- Three initial participant provided information modules: The Basics, Overall Health, & Lifestyle

Physical Measurements

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight
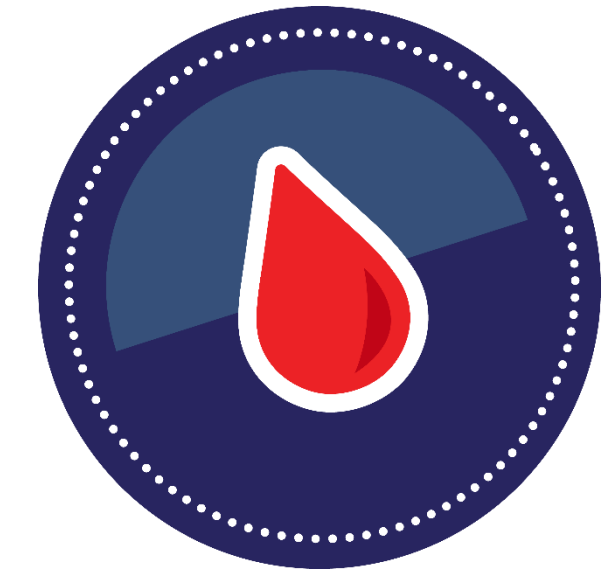
Biosamples

- Blood (or saliva, if blood draw is unsuccessful)
- Urine
- 28 aliquots of blood and 6 of urine stored in Biobank

Two Methods of Enrollment

You learn out about the Research Program

Participant Portal
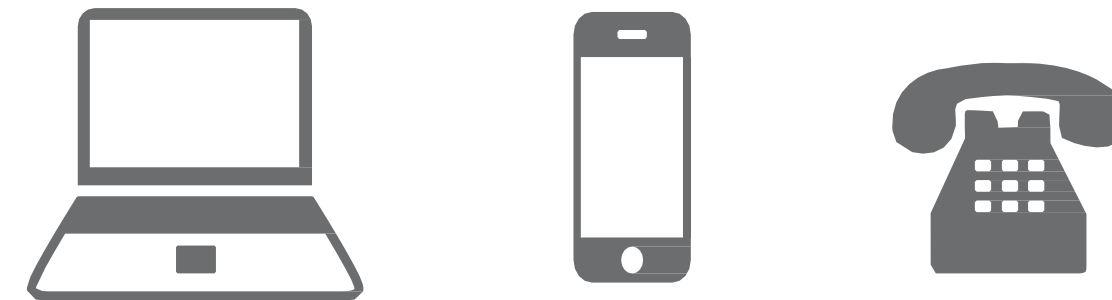
Direct Volunteers

Health Care Provider Organizations

Kinds of Research Activities Participants Are Invited To Do…

1. **Enroll & Consent**
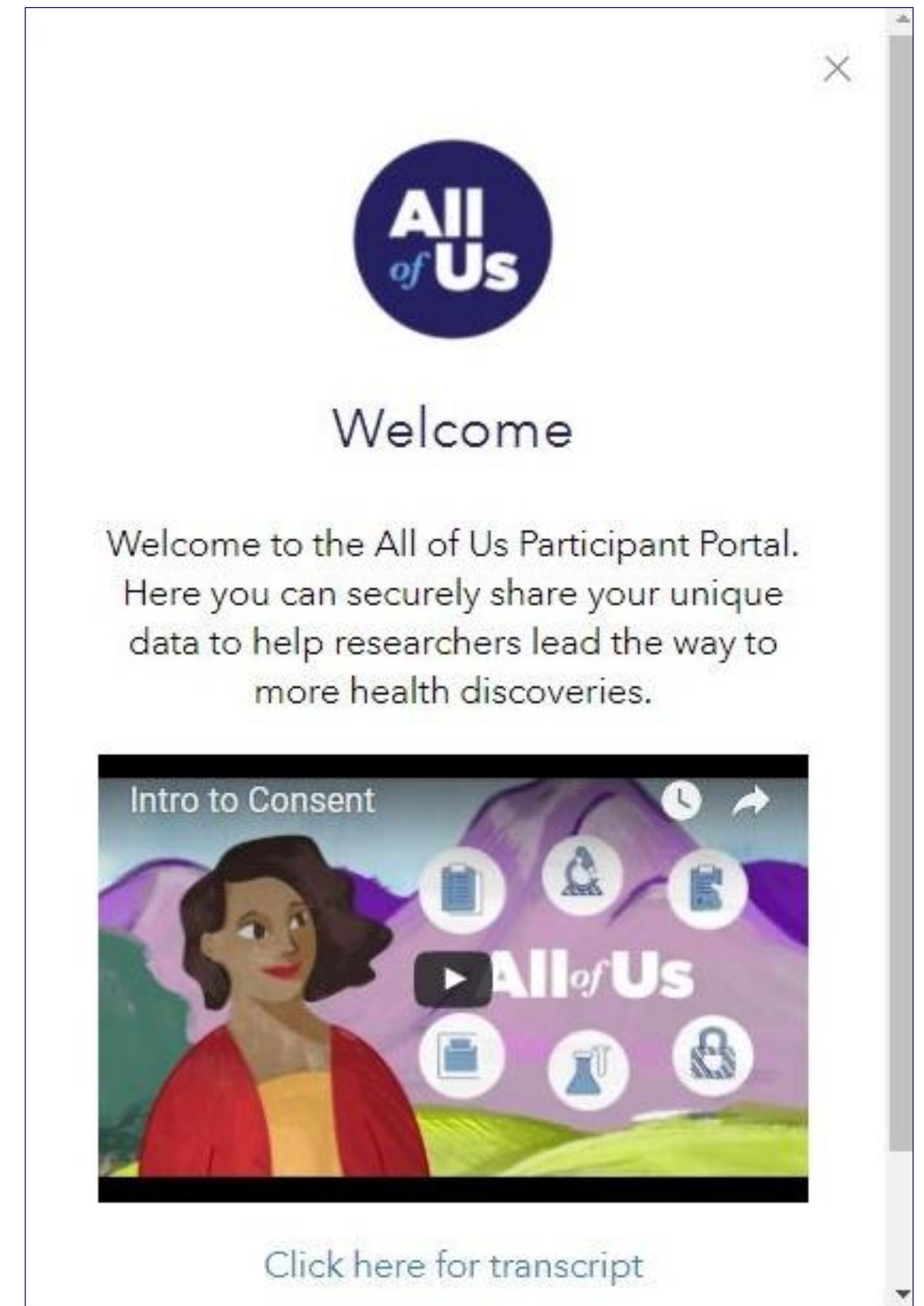
2. **Surveys**

3. **Physical Measurements**

4. **Biosamples**

5. **Apps, Phones & Wearables**

Consent / e-Consent

- Recruit 18+ years old initially; plan to include children in next iteration

- eConsent or paper long-form

- 5th grade reading level; English & Spanish initially

- eConsent process includes modules on:
  - Participant Provided Info (PPI) + Linkage + Re-contact
  - Physical Measurements (PM) + Biospecimen
  - Sensors or wearable devices
  - EHR
  - Genetic information

- Separate opt-in & signature for some modules, including EHR and genetics (state laws)

Welcome

Welcome to the All of Us Participant Portal. Here you can securely share your unique data to help researchers lead the way to more health discoveries.

Intro to Consent

Click here for transcript

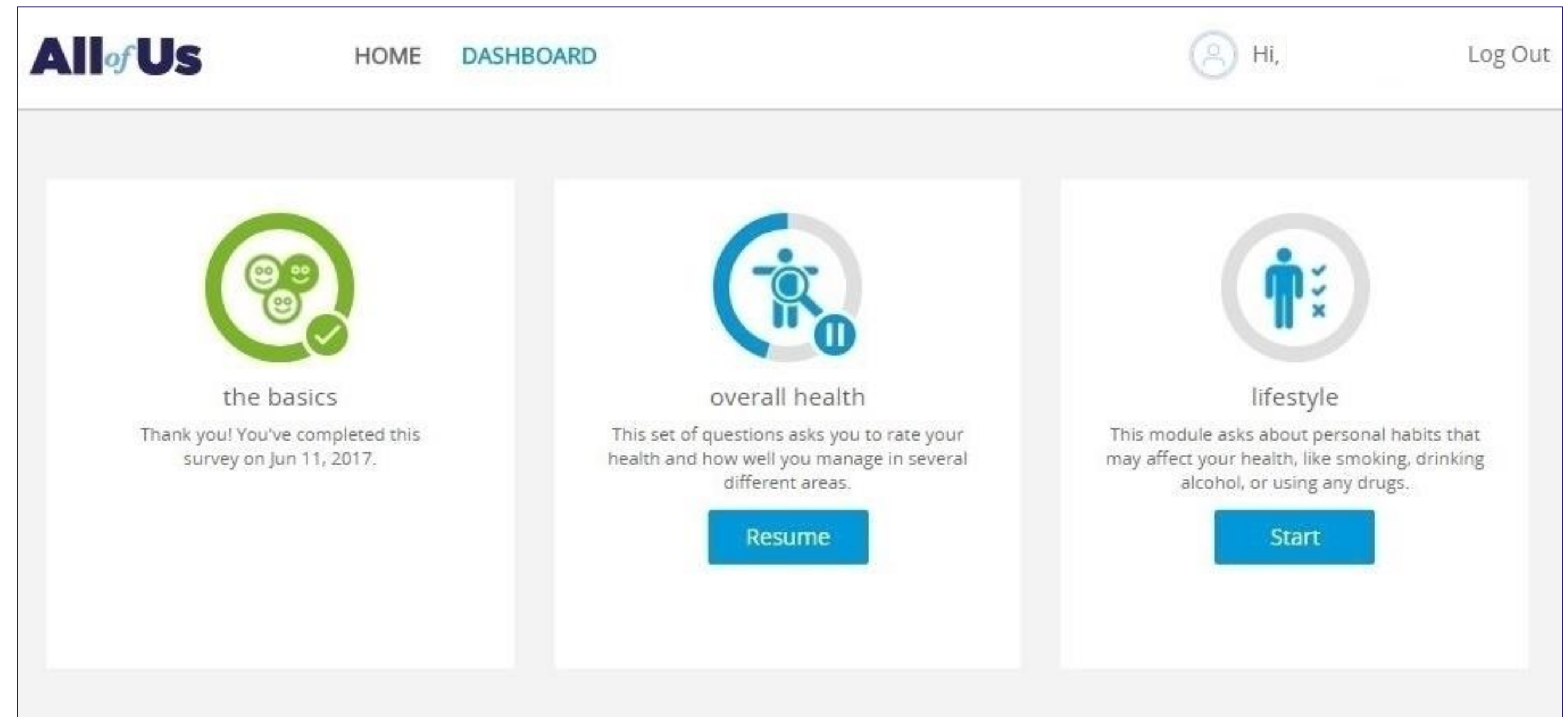# Participant Provided Information

Proposed Enrollment Surveys

1. The Basics

2. Overall Health

3. Lifestyle

In Development

4. Personal Health History

5. Medications

6. Family History

7. Health Care Access and Utilization

8. Sleep

9. Environment and exposures

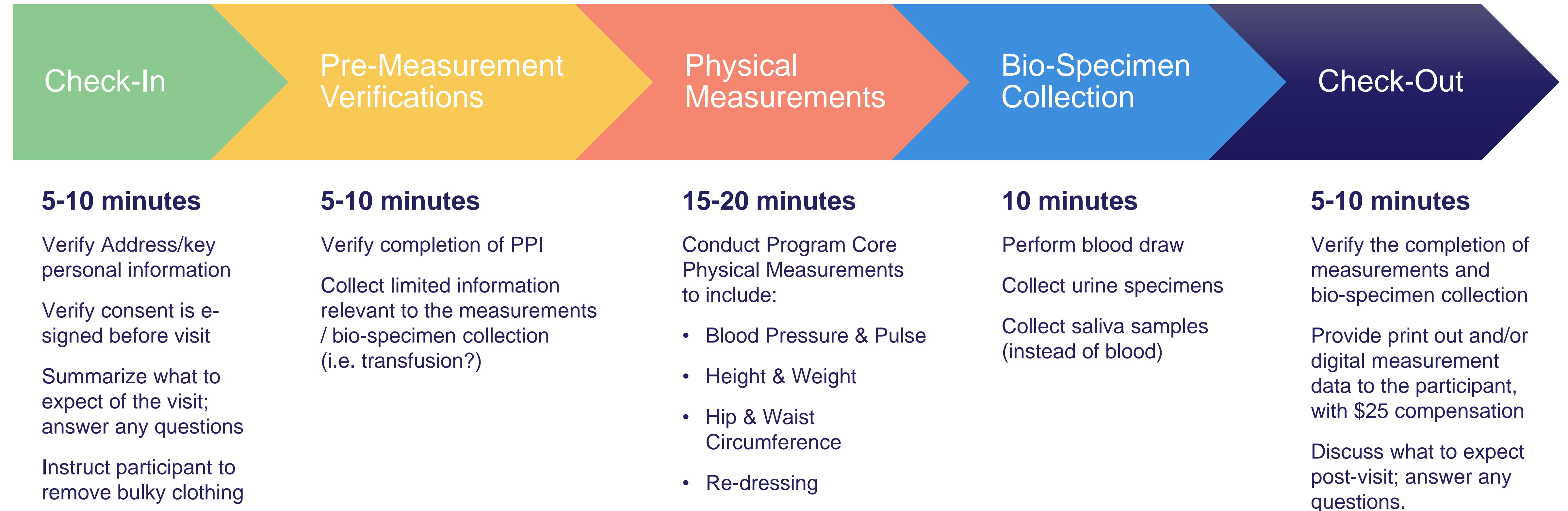**Participant dashboard on their progress**

Electronic Health Records

⊙ Participants will be asked to authorize linkage of their EHR information.

⊙ Participants must sign a separate informed consent to authorize access to their complete EHR.

Initial Data Types	Expanded Data Types (May Include)
• Demographics • Visits • Diagnoses • Procedures • Medications • Laboratory Visits • Vital Signs	• Physician Notes • Mental Health Data • HIV Status • Substance Abuse & Alcohol use/misuse • Genomic Information

SYNC FOR SCIENCE

Clinic Visit

Check-In	Pre-Measurement Verifications	Physical Measurements	Bio-Specimen Collection	Check-Out

5-10 minutes

Verify Address/key personal information

Verify consent is e-signed before visit

Summarize what to expect of the visit; answer any questions

Instruct participant to remove bulky clothing

5-10 minutes

Verify completion of PPI

Collect limited information relevant to the measurements / bio-specimen collection (i.e. transfusion?)

15-20 minutes

Conduct Program Core Physical Measurements to include:

- Blood Pressure & Pulse
- Height & Weight
- Hip & Waist Circumference
- Re-dressing

10 minutes

Perform blood draw

Collect urine specimens

Collect saliva samples (instead of blood)

5-10 minutes

Verify the completion of measurements and bio-specimen collection

Provide print out and/or digital measurement data to the participant, with $25 compensation

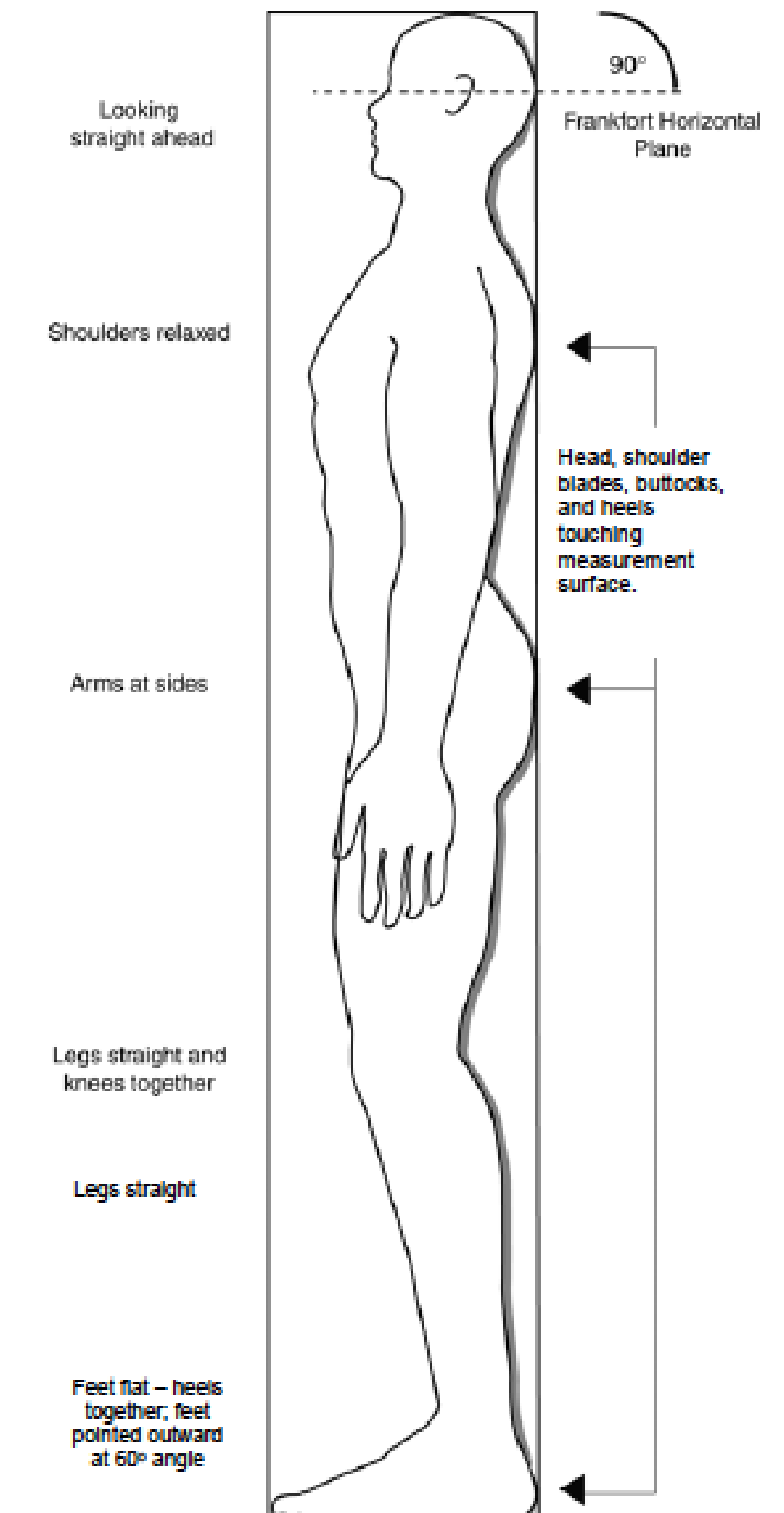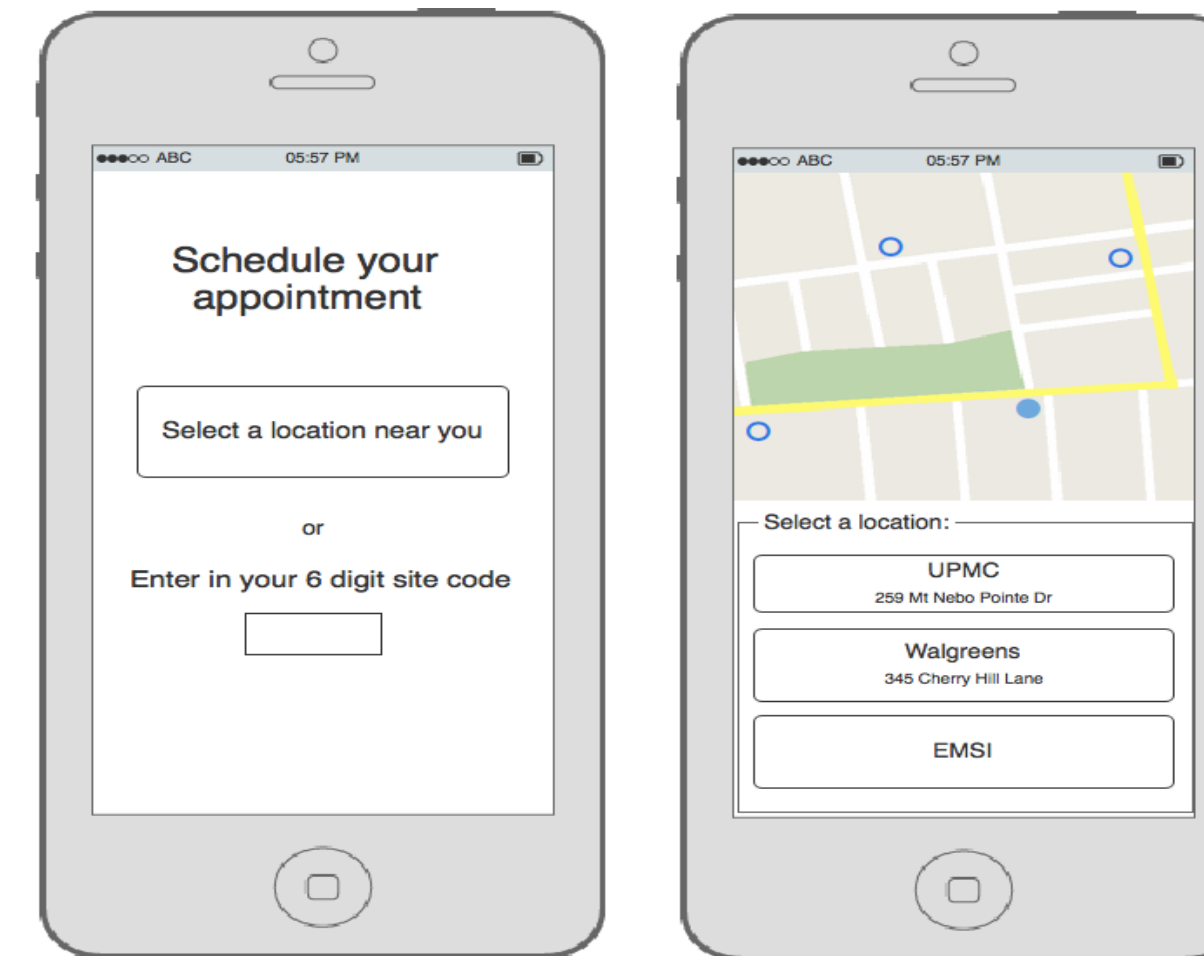Discuss what to expect post-visit; answer any questions.

Version 1 Physical Measurements & Biospecimen Collection

Physical Measurements

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

Biospecimen Collection

- Blood and/or saliva
- Urine
- 34 aliquots stored in Biobank
- 24 hour courier nationwide
- Nights & weekend collections

Biospecimens: Blood and Urine

## Table: PMI Sample Collection
44 ml blood, 34 aliquots to save

Type of sample and collection tube (Collection priority)	Volume Collected (ml)	Transport T°C	Fraction and (number) of aliquots created	Aliquots -80°C	LN2
(1) EDTA	4	4	(2) DNA	0.5 ml	--
(2) EDTA	10	4	(5) Plasma (1) WBC (2) RBC (+glycerol)	1.0 ml	--
(3) Clot Activator (SST)	8	4	(4) Serum	1.0 ml	--
(4) Plasma Separator (PST)	8	4	(4) Plasma	1.0 ml	--
(5) EDTA	10	4	(5) Plasma (1) WBC (2) RBC (+glycerol)	1.0 ml	--
(6) Na-Heparin	4	4	(2) WB (+DMSO)		1.0 ml
Urine	10	4	(6) Urine	1.0 ml	--

◉ Selected processing steps to be done at collection sites
◉ Samples shipped same day of collection; received at Mayo within 24 hours and processed within 40

Minimum amounts of biospecimen collection to be considered enrolled:
◉ 4 mL of blood for DNA + spot urine sample, OR
◉ Saliva sample + spot urine sample, if needle sticks unsuccessful after 2 attempts or in very rare cases when it may not be possible to draw blood

All of Us Data & Specimen Flows
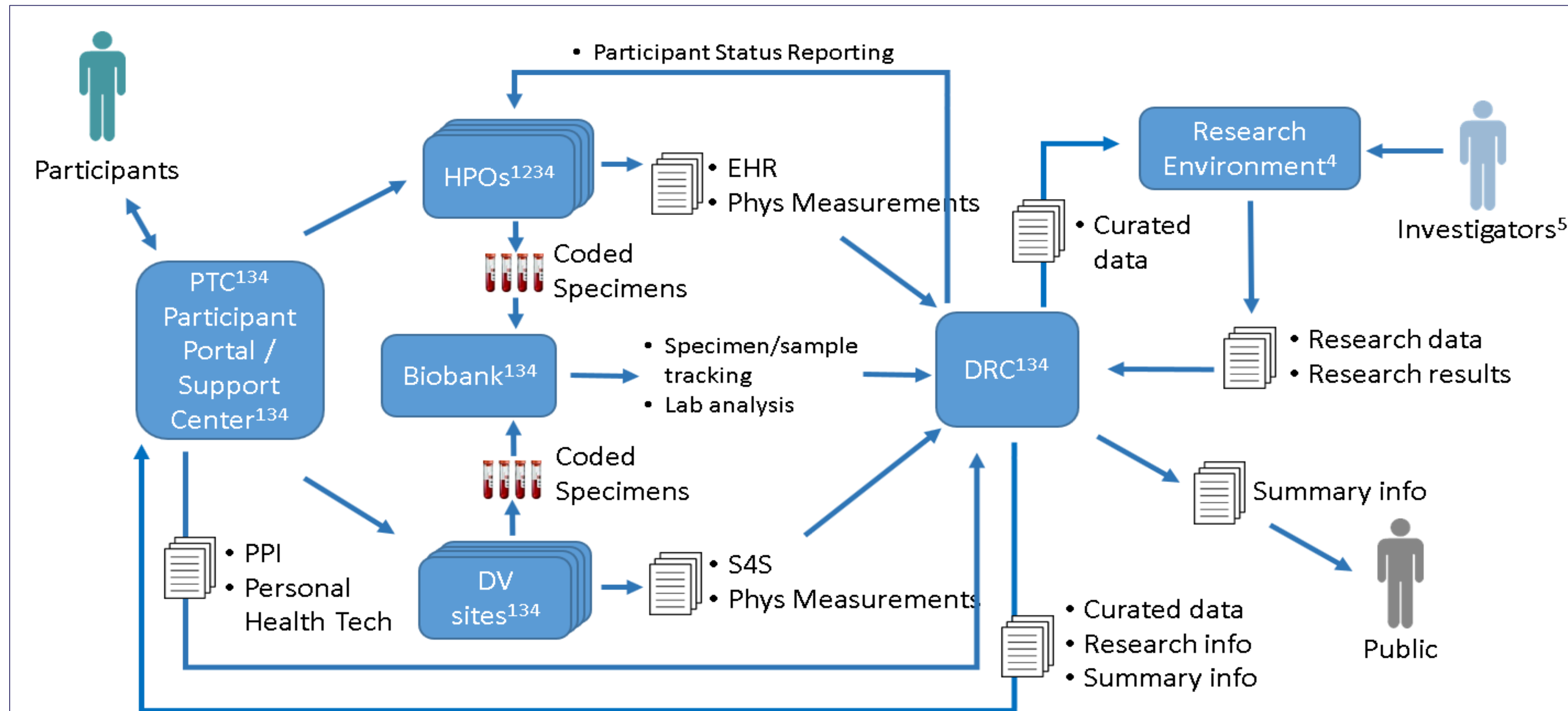
1 = Subject to Common Rule or IRB review
2 = Subject to or follows HIPAA Privacy and Security Rule
3 = Covered by Certificate of Confidentiality
4 = Subject to FISMA security review or Interconnection Security Agreement
5 = Subject to review and conditions of access

PTC = Participant Technologies Center
DRC = Data & Research Center
HPO = Healthcare Provider Organization
DV = Direct Volunteers
PPI = Participant Provided Information
S4S = Sync4Science

All of Us Participant Portal …

- ◉ The Participant Portal is:
  - The core public-facing program enrollment & communications tool
  - **Provides Program updates and messaging to participants**
  - Access of individual-level information

- ◉ Future Portal Version will:

  - Include a dashboard where participants can view their data compared to the aggregated data generated through the *All of Us* Research Program.

Figure 10–2: Data Flow for Participants and HPO Staff

Participant-Facing *All of Us* Portal (website and mobile applications)

Arrow direction indicates source of authorship and destination of data.

Trained Program Staff-Facing HealthPro Portal (website)

Consent Completion → Consent Status

PPI Completion → PPI Status

Physical Measurement Data

Biospecimen Status & Information

EHR Status (where applicable)

Participants will see only their own information

Trained Program Staff will be able to look up individual participants to review individual participant data